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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patentees:

Arlindo L. Castelhano et al.

Patent No.:

7,598,252

Issued:

October 6, 2009

U.S. Serial No:

10/718,280

Filed:

November 20, 2003

For:

COMPOUNDS SPECIFIC TO ADENOSINE A1 RECEPTOR AND

USES THEREOF

30 Rockefeller Plaza, 20<sup>th</sup> Floor New York, New York 10112 November 18, 2009

Mail Stop: Petition

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SIR:

## PETITION TO CORRECT PATENT TERM ADJUSTMENT (PTA) INDICATED IN NOTICE OF ALLOWANCE

The above-identified patent issued October 6, 2009 and on its front page indicates that its patent term is extended under 35 U.S.C. §154(b) by 725 days. It is believed that the correct total Patent Term Adjustment (PTA) under 35 U.S.C. §154(b) is 1,074 days.

11/28/2809 CNGUYEN3 88868663 7598252 81 FC:1455 288.88 OP

The determination of the total PTA of 725 days is erroneous at least because the U.S. Patent & Trademark Office's (PTO) PTA calculator failed to account for two separate non-overlapping Patent Office delays. The two non-overlapping PTO delay periods should have their days added together in accordance with the reasoning in Wyeth et al. v. Dudas, No. 07-1492 (D.D.C. September 30, 2008). The number of PTA credits

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warranted for PTO delay under 35 U.S.C. § 154(b)(1)(A), 37 C.F.R. § 1.702(a)(1) and 37 C.F.R. § 1.702(a)(2) is 528 days (first period). The number of PTA credits warranted for PTO delay under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) is 872 days (second period). Because the mentioned periods of delay do not overlap, Applicants are entitled to PTA credits for the non-overlapping delay under 37 C.F.R. § 1.702(a)(2) and 37 C.F.R. § 1.702(b). Accordingly, a total PTA credit of 1,400 days (i.e., 528 + 872 days) is appropriate based upon the PTO delay.

An application for patent term adjustment under 37 C.F.R. § 1.705 must be accompanied by:

#### 1) The fee set forth in §1.18(e).

Applicants hereby enclose a check for \$200.00 for the fee set forth in §1.18(e).

### 2) A statement of the facts involved, specifying:

i) The correct patent term adjustment and the basis or bases under § 1.702 for the adjustment.

#### PTO Delays

The correct total PTA credit based upon the PTO delays is 1,400 days. The basis for the 528 days PTA credit is under § 1.702(a)(1)-(2) and is due to the PTO's failure to mail a notification under 35 U.S.C. § 132 or a notice of allowance within 14 months of the application's filing date and the PTO's failure to respond to a reply under U.S.C. § 132 not

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later than four months after the date on which the reply was filed. The basis for the 872 days PTA credit is under § 1.702(b) and is due to the PTO's failure to issue a patent within three years of the filing date.

(ii) The relevant dates as specified in § 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled.

#### First Part of PTA Credit

The relevant dates as specified in § 1.703(a)(1) for first part of the PTA credit are as follows: the date of January 20, 2005 which is the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a); and the date of March 14, 2005 which is the mailing date of a first notification under 35 U.S.C. § 132. Thus, the period of delay runs from January 21, 2005 to March 14, 2005. This portion of the first period of delay is 53 days.

The relevant dates as specified in § 1.703(a)(2) are as follows: the date of January 28, 2006 which is the date that is the day after the four months after the September 28, 2005 Amendment In Reply to Non-Final Office Action in compliance with § 1.111 was filed; and the date of May 18, 2007 which is the mailing date of a Non-Final Office Action. Thus, the period of delay runs from January 29,

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2006 to May 18, 2007. This portion of the first period of delay is 475 days.

Accordingly, the total first period of delay is 528 days.

#### Second Part of PTA Credit Not Overlapping with First

The relevant dates as specified in § 1.703(b) for the second part of the PTA credit are as follows: the date of November 20, 2006 which is the day after the date that is three years after the date on which the application was filed under 35 U.S.C. § 111(a); the issue date of October 6, 2009; and the date of May 18, 2007 which is the mailing date of a Non-Final Office Action. Thus, the period of delay runs from November 21, 2006 to October 6, 2009, excluding the number of overlapping days in § 1.703(a)(2) beginning on the date of November 21, 2006 ending and on May 18, 2007. Accounting for the excluded period, the period of delay runs from May 19, 2007 to October 6, 2009. This second period of delay is 872 days.

The total of the first and second periods of not overlapping delay is 1,400 days.

iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer.

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The subject patent is not subject to a terminal disclaimer. See 37 C.F.R. § 1.705(b)(2)(iii).

iv) (A) Any circumstances during the prosecution of the application resulting in the patent that appear to constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

#### Applicant Delay Days

The total number of PTA debits of 326 days for applicant delay that is set forth on the enclosed PTA History (Exhibit A) is correct.

The following statements are required by 37 C.F.R. § 1.705(b)(2)(iv)(A) and list any circumstances during the prosecution of this application which appear to constitute a failure to engage in reasonable efforts to conclude processing or examination of the above-identified patent application as set forth in § 1.704.

i) Applicants' Amendment in Response to a March 14, 2005 Office Action was sent on September 28, 2005 by facsimile under 37 C.F.R. § 1.8 and received by the PTO on September 28, 2005, which is after the three month period for filing a response. Under § 1.704(b), the period of adjustment for delay associated with this reply begins on the day after the date that is three months after the March 14, 2005 date of mailing of the Office Action, i.e. June 15, 2005, and ends on the date the reply was filed,

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- i.e. September 28, 2005. Thus, the period of delay runs from June 15, 2005 to September 28, 2005. This period of delay is 106 days.
- Applicants' Amendment in Response to a May 18, ii) 2007 Office Action was sent on October 18, 2007 by first class mail under 37 C.F.R. § 1.8 and received by the PTO on October 22, 2007, which is after the three month period for filing a Under § 1.704(b), the period response. adjustment for delay associated with this reply begins on the day after the date that is three months after the May 18, 2007 date of mailing of the Office Action, i.e. August 19, 2007, and ends on the date the reply was filed, i.e. October 22, 2007. Thus, the period of delay runs from August 19, 2007 to October 22, 2007. This period of delay is 65 days.
- iii) Applicants' Amendment in Response to a January 9, 2008 Office Action was sent on May 9, 2008 by first class mail under 37 C.F.R. § 1.8 and received by the PTO on May 14, 2008, which is after the three month period for filing a Under § 1.704(b), the period response. adjustment for delay associated with this reply begins on the day after the date that is three months after the January 9, 2008 mailing of the Office Action, i.e. April 10, 2008, and ends on the date the reply was filed, i.e. May 14, 2008. Thus, the period of delay runs from April 10, 2008 to May 14, 2008. This period of delay is 35 days.
- iv) Applicants' Supplemental Information Disclosure Statement was sent on October 16, 2008 by first class mail under 37 C.F.R. § 1.8 and received

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by the PTO on October 20, 2008. Under § 1.704(c)(10), submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of : (i) the number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office Action or notice in response to the amendment under § 1.312 or such other paper; or (ii) four months. Thus, this period of delay is four months, i.e. 120 days.

The total number of PTA debits for applicant delay is 326 days (i.e., 106 + 65 + 35 + 120 days).

Thus, the total PTA under § 1.703(f) is therefore 1,074 days, which is the total PTA credit for PTO delay of 1,400 days less the total PTA debit for applicant delay of 326 days calculated under § 1.704 in detail above.

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#### Conclusion

As discussed above, Applicants submit that the correct patent term adjustment under 35 U.S.C. for the subject §154(b) application is 1,074 days (1400 PTO delay - 326 applicant delay). Accordingly, Applicants respectfully request that the PTO correct the patent term adjustment under 35 U.S.C. §154(b) for the allowed application.

No fee, other than the \$200.00 fee for filing an application for patent term adjustment, is deemed necessary in connection filing of this Petition. with the However, if additional fee is necessary, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Mail Stop: Petition Commissioner for Patents P.O. Box 1450

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uskovember 18, 2009

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# EXHIBIT A

10/718,280	COMPOUNDS SI THEREOF	PECIFIC TO ADE	NOSINE A1 RECEPTORS AND USES	11-16- 2009::15:35:58
<b>Patent Ter</b>	m Adjustments			
Patent Term	Adjustment (PTA) f	or Application Nu	mber: 10/718,280	
Filing or 371(	c) Date:	11-20-2003	USPTO Delay (PTO) Delay (days):	1051
Issue Date of Patent:		10-06-2009	Three Years:	-
Pre-Issue Petitions (days):		+0	Applicant Delay (APPL) Delay (days)	326
Post-Issue Petitions (days):		+0	Total PTA (days):	725
USPTO Adjustment(days):		+0	Explanation Of Calculations	
<b>Patent Terr</b>	n Adjustment I	History		
Date	<b>Contents Desc</b>	ription	PTO(Days	) APPL(Days)
09-16-2009	PTA 36 Months		348	3
10-06-2009	Patent Issue Dat	te Used in PTA Ca	alculation 15	7
09-02-2009	Dispatch to FDC		1	•
09-02-2009	Application Is Co	onsidered Ready 1	for Issue 1	•
09-02-2009	TC Return to Pul	os	1	•
10-20-2008	Information Disc	closure Statement	t considered	•
05-07-2009	Pubs Case Rema	ind to TC	1	•
10-20-2008	Information Disc	losure Statement	t (IDS) Filed	120
04-01-2009	TC Return to Pul	bs		<b>1</b>
04-04-2009	TC Return to Pul	bs		<b>^</b>
01-02-2009	Issue Fee Payme	ent Verified		•
01-02-2009	Issue Fee Payme	ent Received		<b>^</b>
10-20-2008	Pubs Case Rema	and to TC		•
11-25-2008	Correspondence	Address Change		<b>4</b> .
11-25-2008	Filing Receipt - 0	Corrected		<b>^</b>
10-30-2008	TC Return to Pul	bs		<b>^</b> :
10-30-2008	Pubs Case Rema	ind to TC		<b>+</b>
11-04-2008	TC Return to Pul	bs		•
10-20-2008	Reference captu	re on IDS		•
10-20-2008	Information Disc	dosure Statemen	t (IDS) Filed	•
10-20-2008	Information Disc	dosure Statement	t (IDS) Filed	•
10-02-2008	Mail Notice of Al	lowance	18	3
09-30-2008	Notice of Allowa	nce Data Verificat	tion Completed 1	•
09-30-2008	Case Docketed t	o Examiner in GA	AU 1	•
09-30-2008	Document Verifi	cation	1	•
09-30-2008	Examiner's Ame	ndment Commun	ication 1	<b>•</b>
05-14-2008	Information Disc	dosure Statement	t considered 1	•
09-10-2008	Paralegal TD Acc	cepted	1	•
10-22-2007	Terminal Disclai	mer Filed	1	•
08-29-2008	Paralegal TD Acc	epted	1	•
03-01-2005	terminal disclain	ner fee paid	1	•
06-18-2008	Date Forwarded	to Examiner	1	•
05-14-2008	Response after I	Non-Final Action		35
05-14-2008	Request for Exte	nsion of Time - C	Granted	<b>1</b>

05-14-2008	Reference capture on IDS		•
05-14-2008	Information Disclosure Statement (IDS) Filed		•
05-14-2008	Information Disclosure Statement (IDS) Filed		•
01-09-2008	Mail Non-Final Rejection		•
01-07-2008	Non-Final Rejection		
11-05-2007	Paralegal TD Accepted		
10-22-2007	Terminal Disclaimer Filed		
10-22-2007	terminal disclaimer fee paid		
11-01-2007	Date Forwarded to Examiner		
10-22-2007	Response after Non-Final Action		65
10-22-2007	Request for Extension of Time - Granted		•
11-20-2003	Information Disclosure Statement considered		•
11-20-2003	Information Disclosure Statement (IDS) Filed		•
05-18-2007	Mail Non-Final Rejection	475	
03-17-2006	Non-Final Rejection	<b>^</b>	
01-18-2006	Date Forwarded to Examiner	<b>^</b>	
09-28-2005	Response after Non-Final Action		106
01-09-2006	Mail-Petition to Revive Application - Granted		•
10-19-2005	Paralegal TD Accepted		•
09-28-2005	Petition Entered		<b>^</b>
03-14-2005	Reference capture on IDS		<b>+</b>
03-14-2005	Information Disclosure Statement (IDS) Filed		•
03-14-2005	Information Disclosure Statement (IDS) Filed		<b>1</b>
03-14-2005	Mail Non-Final Rejection	53	
03-09-2005	IFW TSS Processing by Tech Center Complete	•	
03-01-2005	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received	•	
11-20-2003	Reference capture on IDS	•	
03-07-2005	Non-Final Rejection	•	
06-15-2004	Case Docketed to Examiner in GAU	•	
11-24-2003	Preliminary Amendment	<b>↑</b>	
02-26-2004	Case Docketed to Examiner in GAU	<b>↑</b>	
01-12-2004	Application Return from OIPE	•	
01-12-2004	Application Return TO OIPE	•	
01-12-2004	Application Dispatched from OIPE	•	
01-12-2004	Application Is Now Complete	•	
01-06-2004	Cleared by OIPE CSR	<b>^</b>	
12-27-2003	IFW Scan & PACR Auto Security Review	<b>↑</b>	
11-20-2003	Initial Exam Team nn	•	

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